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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,951	10/04/2004	Gerardo Perez-Camargo	115808-001	3093
29157	7590	10/17/2007		
BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 10/17/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

## Office Action Summary

Application No.

10/509,951

Applicant(s)

PEREZ-CAMARGO ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Summary*

1. Applicant is reminded that the office has not received IDS as of this date.

Claims 35-68 are pending in this application and claims 35-68 will be prosecuted on the merits.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 35-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of improving or maintaining absorption of vitamin E in a pet comprising feeding the pet with a specific composition comprising intestinal function promoter, pancreatic function promoter and liver function promoter, does not reasonably provide enablement for any edible composition that effects the pet's lipid absorption capacity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). 'Among these factors are: (1) the nature of the invention; (2) the state of

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the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

claim 35 is drawn to a method of improving or maintaining absorption of vitamin E in a pet animal, the method comprising the step of feeding the pet a sufficient amount of an edible composition that effects the pet's lipid absorption capacity.

With respect to the scope of enablement for a method of improving or maintaining absorption of vitamin E in a pet comprising feeding the pet with any composition that effects the pet's lipid absorption capacity is very broad. , The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. *Nationwide Chem. Corp. v. Wright*, 458 F. supp. 828,839, 192 USPQ 95, 105(M.D. Fla. 1976); *Aff'd* 584 F.2d 714,200 USPQ 257 (5t5 Cir. 1978); *In re fischer*, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art.

The claims are very broad due to the vast number of possible Compounds that can be included in the any edible composition.

Although the specification discloses edible composition comprising intestinal function promoter, liver function promoter and pancreatic function promoter", the specification fails to provide how

to make/use any kind of edible composition that effects lipid absorption capacity (with no specific recitation of specific ingredients, without undue amount of experimentation. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fishcher, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823.

The relative skill of the artisan or the unpredictability of the pharmaceutical art is very high. Where the physiological activity of a chemical or biological compound is considered to be an unpredictable art (Note that in cases involving physiological activity such as the instant case, "the scope Of enablement obviously varies inversely with the degree of unpredictability of the factors involved" (See In re fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970))).

The examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP 2164.02). However, given the highly unpredictable state of the art and furthermore, given that the applicant does not provide sufficient guidance or direction as to how to make and use the full scope of the instant claimed invention without undue amount of experimentation, the Office would require appropriate disclosure, in the way of scientifically sound reasoning or the way of concrete examples, as to why the disclosure shown is a reasonably representative and objective showing such that it was

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commensurate in scope with and, thus, adequately enables, the use of the claimed composition for the full scope of the presently claimed subject matter. In the absence of such guidance and evidence or reasoning, the specification fails to provide an enabling disclosure.

As discussed above, considering above factors, especially the "sufficient working examples", "the level of skill in the art", "the relative skill and the unpredictability in the pharmaceutical art", "breadth of the claims" and "the chemical nature of the invention", one having ordinary skill in the art would have to undergo an undue amount of experimentation.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 35-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the "edible composition". The metes and bounds of the claim are not defined. It is not clear which components/compounds are included in the claim. Claim 37 recites the limitation "pancreatic extract". The chemistry of the pancreatic extract is not clear. The specificity of the claim is missing; Applicant is requested to make corrections.

***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 35-68 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,471,999 in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of Hevia (US 2006/0052454 A1) and US patent No. (6,013,665).

'999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26). '999 teaches including an alkali in the milk-based powder, which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14). '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder,

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galactosidase (lactase amino), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats. '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches omega fatty acids such as soybean oil and in Examples 1-2 (col. 3, lines 15-20).

'999 does not teach glutathione. However, 571 or 412 teach glutathione.

'571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals. '571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41).

Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).

The references disclosed above do not teach lipid assimilation, however, Hevia teaches lipid digestion due to bile salts which are emulsifying agents and emulsifiers are claimed as liver function promoter.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate emulsifying agents such as bile salts to help in lipid digestion and assimilation because emulsifying agent helps in lipid digestion. A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter in order to help in lipid assimilation with a reasonable expectation of success.

Hevia does not teach vitamin E absorption. However, US Patent (6,013,665) teaches an invention relating to enhancing the absorption and transport of lipophilic compounds such as vitamin E in an animal with a combined administration of vitamin E with lecithin (abstract and summary).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate lecithin and vitamins in the composition forwarded by the above references because it helps in vitamin e absorption. A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase vitamin E absorption.

8. Claims 35-68 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al WO 02/15719 ('719) in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of Hevia (US 2006/0052454 A1) and (US Patent No. 6, 013,665).

'719 discloses a method of treatment which comprises administering an effective amount of the composition which contains whey protein (an intestinal mucoas function promoter according to

applicant) to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21). Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). , '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30). '719 teaches including taurine and vitamins (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), '719 teaches a lipid source including omega-3 fatty acids (abstract, claim 1). , '719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2). '719 does not teach glutathione. However, 571 or 412 teach glutathione. However, '571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals.

The reference does not teach glutathione.

'571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals. '571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41). Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function

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promoter. '571 teaches that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).

The references do not teach lipid assimilation, however, Hevia teaches lipid digestion due to bile salts which are emulsifying agents and emulsifiers are claimed as liver function promoter.

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Hevia does not teach vitamin E absorption However, US Patent (6,013665) teaches an invention relating to enhancing the absorption and transport of lipophilic compounds such as vitamin E in an animal with a combined administration of vitamin E with lecithin (abstract and summary).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate lecithin and vitamins in the composition forwarded by the above references because it helps in vitamin e absorption. A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and

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intestinal function promoter with a reasonable expectation of success in order to help increase vitamin E absorption.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

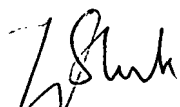
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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